IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO

THE UNITED STATES OF AMERICA, and

THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, AND WASHINGTON; THE DISTRICT OF COLUMBIA; THE COUNTY OF ALLEGHENY; AND THE CITIES OF CHICAGO, NEW YORK, AND PHILADELPHIA,

ex rel. JOEL STEVENS

Plaintiffs,

v.

ATRICURE, INC., ST. HELENA HOSPITAL, AND ADVENTIST HEALTH,

Defendants.

CASE NO. 1:22-cv-284-MRB

Judge Michael R. Barrett

REPLY IN SUPPORT OF ATRICURE'S MOTION TO DISMISS THE FOURTH AMENDED COMPLAINT

INTRODUCTION

Relator's Opposition to AtriCure's Motion to Dismiss his Fourth Amended Complaint serves only to confirm that even after amending his complaint four times, Relator still cannot plead a viable claim against AtriCure under the False Claims Act ("FCA"). Not only should AtriCure's motion be granted, it is plain that entertaining further amendments would be futile and that the dismissal should be with prejudice.

The FCA "attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment." *U.S. ex rel. Sheldon v. Kettering Health Network*, 816 F.3d 399, 411 (6th Cir. 2016) (cleaned up). The Sixth Circuit has thus adopted a "clear and unequivocal requirement that a relator allege specific false claims when pleading a violation of the FCA." *U.S. ex rel. Owsley v. Fazzi Assocs., Inc.*, 16 F.4th 192, 196 (6th Cir. 2021), *cert. denied* (Oct. 17, 2022).[1] That can be done "one of two ways." *Id*. "The default rule" is that a relator "must identify a representative claim that was actually submitted to the government for payment." *Id*. "Alternatively, a [relator] can otherwise allege facts—based on personal knowledge of billing practices—supporting a strong inference that *particular identified claims* were submitted to the government for payment." *Id*. (italics in original).

The operative Complaint, however, does neither, as the Opposition all but concedes. Relator does not dispute that he has failed to identify a representative false claim that was actually submitted to the government. And as a former salesperson working for AtriCure, he cannot claim to have personal knowledge of the billing practices of the doctors and hospitals alleged to have submitted false claims. He instead asks the Court to assume that, because patients old enough to

[1] Throughout this brief, internal quotations, citations, and alterations have been omitted, and all emphasis has been added, unless otherwise noted.

qualify for Medicare were scheduled for surgeries, a claim for payment in an unknown amount was submitted to an unknown government payor, on an unknown date, by an unknown person. But this is precisely the sort of assumption piled on assumption the Sixth Circuit has consistently rejected when offered by plaintiffs, who, like Relator, lack personal knowledge of billing practices and offer pled conclusions in leu of particularized facts identifying claims.

Nor does the Complaint sustain a plausible inference that any such claim would have been "false"—an independent reason to dismiss. That AtriCure provides remuneration to medical professionals is no secret (the Complaint itself asserts payments are a matter of public record). But providing remuneration is not in and of itself either a violation of the Anti-Kickback statute ("AKS") or a viable basis for an FCA action: the Relator must plead facts showing that the payments were given for an improper purpose, as well as facts showing they resulted in the submission of specific claims for payment to the federal government. Relator's conclusory assertions that various expenses were "kickbacks in violation of the AKS" and that such "inducements were effective" are not facts and plainly insufficient to plead an AKS violation with particularity.

In sum, Counts One, Two, and Three fail because Relator has not (a) pled the submission of a false claim with particularity, (b) connected any sufficiently pled claim to any kickback scheme, or (c) pled that any remuneration offered to a provider was intended, even in part, to induce the use of AtriCure products or the submission of claims to Medicare. Count Two (False Records) also fails because the Complaint does not to plead with particularity any false writing or statement, a point which the Opposition does not dispute. Count Three (Conspiracy) additionally fails because the Complaint does not plead the existence of a plan or agreement between the Defendants to violate the FCA. Finally, Counts Four through Thirty-Seven are local analogs to the

FCA and thus fail for the same reasons as Count One, and because the Complaint does not identify a single false claim submitted to any state or local payor.

ARGUMENT

I. RELATOR FAILS TO IDENTIFY A SINGLE FALSE CLAIM

It is undisputed that Relator has not satisfied the Sixth Circuit's default rule for pleading a false claim with particularity by "identify[ing] a representative false claim that was actually submitted to the government." *U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 914 (6th Cir. 2017); *see also*, *Owsley*, 16 F.4th at 196, Relator's Opposition (hereinafter "Opposition" or "Opp.") at 14-19, Doc. 100 at PageID 411-16. While an exception to this "default rule" exists, it is construed narrowly and applies only where the relator has "detailed personal knowledge of the submitting entity's billing practices." *U.S. ex rel. Crockett v. Complete Fitness Rehab., Inc.*, 721 F. App'x 451, 458 (6th Cir. 2018). That is certainly not the case here. As a former salesperson for a medical device company—a company that does not submit claims for reimbursement to Medicare or other payors—Relator has no insight into whether specific providers submitted particular claims for payment to the government. *Cf. U.S. ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 838 F.3d 750, 770 (6th Cir. 2016) ("Prather was hired to work . . . through a backlog of Medicare claims," "review[ed] the documentation for those Medicare claims, in anticipation of them being submitted to Medicare," and "received confirmation that the final claims that she reviewed were submitted for payment.").

Undeterred by the enormous weight of Sixth Circuit authority against him, Relator attempts to rely on two cases from this District, *Millennium Radiology* and *Lynch*, which he claims stand for the proposition that personal knowledge is not necessary to support an inference that a false claim was submitted. This argument fails for two reasons. *First*, the standard Relator attempts to advance is nowhere to be found in these cases and directly at odds with recent Sixth Circuit

precedent. *Second*, these cases, along with *Prather*, are clearly distinguishable on their facts. Relator's decision to rely on them so heavily does not cure the deficiencies endemic to his Complaint—it highlights them.

A. *Millennium Radiology* and *Lynch* Do Not Excuse the Relator from Showing Personal Knowledge of the Facts Underlying his Complaint

The Sixth Circuit has long held that "particularized allegations of an actual false claim is an indispensable element of a FCA violation, and must be specifically pled if a complaint is to survive Rule 9(b) scrutiny." *U.S. ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 505 (6th Cir. 2007). Thus, "at a minimum, the complaint must allege the time, place, and content of the alleged misrepresentation." *Id.* (emphasis in original). In *Prather*, the Sixth Circuit relaxed this standard in a single narrow circumstance: namely, where Relator can allege specific facts "based on personal knowledge of billing practices—supporting a strong inference that particular identified claims were submitted." 838 F.3d at 769–70.

In subsequent decisions, the Sixth Circuit continues to emphasize the limited applicability of the *Prather* exception. *See Ibanez*, 874 F.3d at 915; *U.S. ex rel. Hirt v. Walgreen Co.*, 846 F.3d 879, 881 (6th Cir. 2017). Indeed, just last year it confirmed that a relator can "identify any specific claims" submitted in just "one of two ways." *Owsley*, 16 F.4th at 196. A relator must either (1) "identify a representative claim that was actually submitted to the government" or (2) "allege facts—based on personal knowledge of billing practices—supporting a strong inference that particular identified claims were submitted to the government for payment."[2] *Id.* (emphasis in original).

[2] While the *Owsley* relator did allege "personal knowledge of billing practices," as well as "several instances of upcoding from 2015" involving specific Medicare and Medicare Advantage patients whose diagnoses were improperly changed, the Sixth Circuit affirmed dismissal because she did not sufficiently plead "any specific fraudulent claims" because her complaint "identifie[d] neither the dates on which she reviewed the OASIS forms for these patients, nor the dates of any related claims for payment, nor the amounts of any of those claims." *Id*. at 196-97.

Despite predating *Owsley*, this Court's decisions in *Millennium Radiology* and *Lynch* are not contrary. Relator's assertion that these decisions somehow dispense with the personal knowledge requirement relies on a strained misreading that would require this Court to depart from binding Sixth Circuit precedent. In reality, both cases stand only for the proposition that "[w]hile establishing 'personal knowledge' is one way to create an inference that a claim was submitted, it is not the only means" as the relator remains free to instead **"**provide[] examples of specific false claims submitted to the government." *Millennium Radiology*, 2014 WL 4908275, at *9. In other words, a relator need not rely on the *Prather* exception to the Sixth Circuit's test if he can meet the default 9(b) particularity standard by identifying "specific false claims submitted to the government." *Id.*

Accordingly, both *Millennium Radiology* and *Lynch* are consistent with *Owsley*'s recognition that a relator can "identify . . . specific claims" in just "one of two ways." *Owsley*, 16 F.4th at 196. Relator's failure to identify a specific false claim submitted to the government, paired with his lack of personal knowledge of hospital or physician billing practices, dooms his Complaint.

B. *Millennium Radiology*, *Lynch*, and *Prather* Are Clearly Distinguishable on their Facts

Even a cursory read of *Millennium Radiology* and *Lynch* demonstrates that they are readily distinguishable on their facts. In *Millennium Radiology*, the relator relied on defendant's internal monthly "aging reports," which specifically showed that the defendant had "submitted claims for payment to the government, the amounts submitted and the times submitted," which he also attached to his complaint. *Id.*; *see* Complaint, *Millennium Radiology*, No. 1:11-cv-825 (S.D. Ohio Sept. 30, 2014), ECF 46-5, 46-6. In *Lynch*, the relator similarly "provid[ed] a log showing the patient information, date of service, amount, and payment status for all [procedure] billings

presented to government health care programs for payment during the relevant period." *U.S. ex rel. Lynch v. Univ. of Cincinnati Med. Ctr., LLC*, No. 1:18-cv-587, 2020 WL 1322790, at *27-28 (S.D. Ohio Mar. 20, 2020). That log was supported by an email from the defendant's medical director stating "[w]e will be billing only Medicare (not the patient)" for one of the procedures confirmed on the case log. *Id.* at *29 (emphasis in original).

In the Complaint at issue here, Relator offers nothing even close to the detailed logs of Medicare claims provided in *Millennium Radiology* and *Lynch*. Out of all the various "kickback schemes" mentioned in his complaint, Relator identifies just five procedures that he even attempts to allege were billed to the government. For four of those procedures, Relator alleges generally that the patient "was insured by Medicare. . . such that CMS was billed for the entire surgery, including for AtriCure's products." Relator's Fourth Amended Complaint (S.D. Ohio July 12, 2022), Doc. No. 88 ("Compl.") ¶ 245. With respect to the fifth, Relator merely alleges that a device was "preauthorized" by some unknown Veterans Affairs ("VA") employee for a "scheduled" procedure on an unknown patient. *Id.* ¶ 254. But these conclusory allegations are really nothing more than pled assumptions, and fall far short of the facts needed to support an inference that a "particularly identified claim" was submitted to the government.

First, the only fact Relator provides to support his inference that these unidentified patients were insured by Medicare is their age.[3] *See, e.g., id.* ¶¶ 239, 249. But Relator cannot plead the submission of a false claim based on "declaratory statements . . . that Defendants 'billed Medicare for services covered by Medicare' and submitted 'false and/or fraudulent statements and claims to Medicare for reimbursement.'" *U.S. ex rel. Sharma v. Miraca Life Scis., Inc.*, 472 F. Supp. 3d 429,

[3] Relator does not even allege that a patient involved in one of the two surgeries that was actually performed was "covered by Medicare" during the pertinent year. Compl. ¶ 249 (unknown "procedure" performed on May 22, 2015 on patient "Relator alleges . . . was on Medicare throughout 2014, such that CMS was billed").

444 (N.D. Ohio 2020); *see also U.S. v. Orthopedic All., LLC*, No. CV 16-3966, 2020 WL 6151084, at *7 (C.D. Cal. July 13, 2020) ("Again, the fact that many patients would qualify for Medicare, even coupled with the payment scheme and allegedly sham contracts, does not constitute reliable indicia that lead to a strong inference that claims were actually submitted.").

Second, even if these patients were covered by Medicare, Medicare is a secondary payer only, meaning Medicare is not billed for a procedure if another provider is expected to pay. *See Stalley v. Methodist Healthcare*, 517 F.3d 911, 915 (6th Cir. 2008). A mere allegation that a patient is covered by Medicare or Medicaid is insufficient support for an inference that a claim was actually submitted to the government. *See Ibanez*, 874 F.3d at 921 ("[R]elators allege that, because D.M. had been a Medicaid beneficiary for nearly all of his life, the prescription was reimbursed by Ohio Medicaid. But … we are not to simply assume a claim was presented to the government because relators say so."); *accord Crockett*, 721 F. App'x at 457 (affirming dismissal of FCA complaint where relator provided care specifically to Medicare patients but did not "allege with the particularity required by Rule 9(b) that a specific false claim was [actually] submitted to the United States").

Third, despite speculating that these procedures were billed to Medicare, Relator does not allege that three of the procedures actually occurred. All Relator alleges in his Complaint is that the procedures were "scheduled," Compl. ¶¶ 245-46, which he begrudgingly concedes does not mean that the surgery was "in fact performed on the scheduled date." Opp. at 18, Doc. 100 at PageID 415. It is common knowledge that surgeries are moved, cancelled, or changed all the time; patients are triaged based on need, patients fall ill necessitating postponement of the surgery, and so on.[4] In any event, even if Relator could show that the surgeries occurred, the surgeries

[4] Relator suggests that a citation to the Sixth Circuit's decision in *USN4U, LLC v. Wolf Creek Fed. Servs., Inc.*, 34 F.4th 507 (6th Cir. 2022), is "conspicuously" absent from AtriCure's opening brief. Opp. at 18, Doc. 100 at PageID

themselves are not enough to support an inference that a particular identified claim for payment was ever submitted to Medicare or any other governmental payor.

Fourth, unlike the logs provided in *Millennium Radiology* and in *Lynch*, Relator admits that the only information he can provide for each patient is a date of birth, which cannot be used to identify specific patients, let alone claims.[5] This limited information is insufficient to give AtriCure "fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

In addition, the court in *Lynch* went out of its way to distinguish the detailed information provided by that relator from the facts alleged in *Chesbrough v. VPA, P.C.*, 655 F.3d 461 (6th Cir. 2011)—a case much closer to the facts alleged here. Like the claims at issue in *Chesbrough*, Relator's claims would "'require[] a series of assumptions,' including that the [procedures] were performed on Medicare or Medicaid patients, and could therefore have been billed to the government." *Lynch*, 2020 WL 1322790, at *27 (quoting *Chesbrough*, 655 F.3d at 471). Thus, "considering the need to draw these assumptions," the alleged facts simply cannot "support a

415. Not so. The inference Relator cites pertains to the start date for a project, not whether the plaintiff sufficiently alleged the submission of a false claim. *USN4U*, 24 F.4th at 514 n.2. In contrast, the question here is whether by pleading that a surgery was scheduled, Relator has pled sufficient facts to support the inference he suggests—that the surgery actually occurred and resulted in a false claim. *See, e.g., U.S. ex rel. Harper v. Muskingum Watershed Conservancy Dist*., 842 F.3d 430, 438 (6th Cir. 2016) ("Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief."); *U.S. ex rel. Sheoran v. Wal-Mart Stores E., LP*,858 F. App'x 876, 878 (6th Cir. 2021) ("Rule 9(b) requires far more than mere speculation."); *U.S. ex rel. Marlar v. BWXT Y-12, L.L.C.*, 525 F.3d 439, 445–46 (6th Cir. 2008) (a "general allegation, 'on information and belief,' that [defendant] submitted purported false claims to the government" is insufficient to plead presentment with particularity).

[5] The Opposition also touts that Relator "provides specific batch/lot numbers and/or prices of the materials billed for" with respect to certain "claims." Opp. at 16, Doc. 100 at PageID 413. However, CMS does not actually pay doctors or hospitals for devices used in procedures—it pays the doctor based on the professional services code (CPT) and the hospital based on the patient's diagnosis code (DRG). *See* Compl. ¶ 169 (the "DRG-based reimbursement to the hospital" is unchanged by the cost of the devices used therein); *id.* ¶216 (per AtriCure's "Most Common 2-Stage AFIB Ablation Scenario" estimation, "Medicare reimburses cardiothoracic surgeons approximately $1,700 for the professional fee component of CPT code 33266," one code associated with surgical ablation). In no way does the lot number or sales price of devices that are not billed to the government help identify a particular claim submitted to the Government. Any inference Relator may be trying to create by confusing the price of certain devices with an alleged amount billed to the government can withstand no level of scrutiny.

strong inference—rather than simply a possibility—that a false claim was presented to the government." *Id.* (quoting *Chesbrough*, 655 F.3d at 471).

In his Opposition, Relator also attempts to rely on *Prather*, but the Sixth Circuit has specifically rejected the application of that case to salespeople like Relator who "did not directly engage with claims whatsoever." *See Ibanez*, 874 F.3d at 916. Relator points to the existence of a spreadsheet that "explained to hospitals and physicians the manner in which the hybrid procedure would be reimbursed by Medicare and was intended to promote it over alternative treatment," Opp. at 18, Doc. 100 at PageID 415, but that document does not support an inference that any "particular identified claim" was submitted to Medicare for payment. Likewise, the provision of billing consultant services does not suggest that any "particular identified claim" was submitted to Medicare—especially considering Relator's concession that these services were not limited to government payors. *See* Compl. ¶ 137. Moreover, this "additional evidence" does not demonstrate personal knowledge of the billing practices of the providers and thus Relator's reliance on the *Prather* exception must fail. *Cf. U.S. ex rel. Eberhard v. Physicians Choice Lab'y Servs., LLC*, 642 F. App'x 547, 552-3 (6th Cir. 2016) (affirming dismissal of Complaint based on evidence showing that "Medicare and Medicaid paid in excess of 50%" of the claims because Relator had no "personal knowledge of billing practices or contracts with the government").

In short, the facts alleged by Relator in this case do not even come close to the facts alleged in *Prather*, *Millennium Radiology*, and *Lynch*. Relator's failure to supply the particularity required in the Sixth Circuit requires dismissal of Counts One, Two, and Three.

II. RELATOR CANNOT POINT TO FACTS SUFFICIENT TO SHOW THAT A PARTICULARIZED VIOLATION OF THE ANTI-KICKBACK ACT RESULTED IN A CLAIM FOR PAYMENT TO THE GOVERNMENT

Even if Relator had successfully pled the submission of a claim (he has not), it would only be a false claim if it resulted from an AKS violation, which must also be pled with particularity. *See, e.g., U.S ex rel. Antoon v. Cleveland Clinic Found.*, 978 F. Supp. 2d 880, 893 (S.D. Ohio 2013); *Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 400 (6th Cir. 2015). Relator attempts to skirt this fundamental requirement by asking this Court to assume that payments to specific doctors were actually illegal kickbacks, which resulted in surgeries for which claims for payment were submitted to the government. In other words, Relator's argument is assumptions all the way down. Relator has not pled with particularity requisite facts to convert the routine, publicly disclosed payments he recites into illegal kickbacks resulting in the submission of claims to government payors. Dismissal is warranted for this independent reason.

A. Relator Has Not Pled A Claim "Caused By" an AKS Violation

A relator must not only plead facts showing at least one representative claim was submitted to the government, he must also show that the same claim resulted from a well-pled violation of the AKS. *Ibanez*, 874 F.3d at 915–16; *see also, U.S. ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 835 (8th Cir. 2022) ("resulting from … expresses a but-for causal relationship"); *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 100 (3d Cir. 2018) ("Even if we assume [defendant] paid illegal kickbacks, that is not enough to establish that the underlying medical care … was connected to a breach of the Anti-Kickback Statute; we must have some record evidence that shows a link between the alleged kickbacks and the medical care received[.]").

The Opposition largely ignores this requirement, besides reiterating that AtriCure reimbursed food, travel, and lodging costs for two doctors, the doctors "were able to repay those

inducements by using tens of thousands of dollars' worth of AtriCure's products in Medicare-reimbursed procedures," and that the doctors scheduled or performed five surgeries after AtriCure paid for meals and travel to St. Helena. Opp. at 6-7, Doc. 100 at PageID 403-04, *see also id*. at 11, PageID 408. But glaringly absent are factual allegations that could support Relator's conclusion that the surgeries "resulted from" the remuneration. For example, he has not identified anyone at AtriCure who invited Drs. Tripathi and Kumpati to meals and trips intending to induce referrals for federal healthcare business, what products or procedures the trips and meals were intended to induce, or any overlap with the purported surgeries—let alone any suggestion that the surgeries were performed pursuant to an exclusive referral agreement premised on the meal and trip payments, was alleged in *Millennium Radiology*.[6] 2014 WL 4908275, at *1, *7.

More fundamentally, Relator has not pled that these specific doctors had any role in selecting AtriCure devices for the surgeries or the hospitals' procuring those devices. *Cf.* Compl. ¶ 107 (device selection "usually" involved a "new product committee" at a hospital); *see also, Cf. Jones-McNamara*, 630 F. App'x at 402 ("McNamara did not identify a single employee with authority to make referrals to Life, let alone one who also attended one of Holzer's employee wellness fairs and consumed a Life-sponsored hotdog or hamburger."). At base, reading out Relator's labels and conclusions as *Iqbal* requires, the only relationship between the reimbursements and the purported surgeries alleged is purely temporal: in the year after AtriCure paid for Drs. Tripathi and Kumpati's meals and travel to St. Helena, those heart surgeons scheduled and/or performed heart surgeries. Without more, Relator has not pled facts necessary to support

[6] The Opposition not only fails to rehabilitate the flaws in the chain of causation AtriCure identified that are specific to his VA allegation, *see* Mot. to Dismiss at 14, Doc. 91-1 at PageID 308, it exacerbates them by characterizing that procedure as "non-elective," Opp. at 18, Doc. 100 at PageID 415. As CMS pays doctors for the procedures they do, not the devices they use, *see* Compl. ¶ 169, the "non-elective" nature of such surgeries makes a nexus between AtriCure's payments to these doctors and purported claims resulting from subsequently scheduled or performed surgeries even less plausible.

the inference that any of the five surgeries (to the extent they happened) "resulted from" illegal food and travel payments, let alone that they resulted in the submission of false claims to the government.

Relator fails to offer even a temporal nexus connecting any of the myriad other distinct kickback schemes alleged in the Complaint with specific claims. The Sixth Circuit construes fraudulent schemes "as narrowly as is necessary to protect the policies promoted by Rule 9(b)." *Bledsoe*, 501 F.3d at 510. To sustain an FCA action with respect to a fraudulent scheme, a Relator must plead the submission of a claim which is a "characteristic example[] . . . illustrative of the class of all claims covered by the fraudulent scheme." *Id.* The test for whether a claim is a sufficiently "characteristic example" to permit a relator to proceed to discovery on a particular scheme is that it "in all material respects, including general time frame, substantive content, and relation to the allegedly fraudulent scheme, be such that a materially similar set of claims could have been produced with a reasonable probability by a random draw from the total pool of all claims." *Id.* at 511; s*ee also U.S. ex rel. Suarez v. AbbVie, Inc.*, No. 15-cv-8928, 2019 WL 4749967, at *13 (N.D. Ill. Sept. 30, 2019) ("Relator cannot ask the court to infer that the fraud occurred nationwide based on allegations concerning only South Florida."). Here, there are no allegations that Drs. Tripathi or Kumpati received or were offered consulting agreements, hourly or event-based fees, payments for off-label procedures, grants, free disposable or capital equipment, or marketing assistance prior to scheduling or performing the five surgeries, let alone in exchange for the same.[7] *See* Compl. ¶ 89. Nor are there allegations that a hospital received a

[7] Although Dr. Kumpati purportedly received billing support services, "billing assistance tailored to the purchased products, reimbursement consultation, and other programs specifically tied to support of the purchased product" do not violate the AKS unless they are offered "in tandem with another service or program that confers a benefit on a referring provider (such as a reimbursement guarantee that eliminates normal financial risks)." *Suarez*, 2019 WL 4749967, at *6. Further, Relator's argument that the billing counseling Kathryn Barry provided on August 18, 2015 is somehow connected to a VA surgery is directly contradicted by the Complaint. *See* Compl. ¶ 140 (alleging that "on August 18, 2015, Ms. Barry spoke directly to James Kelley, the Administrator for Cardiac Surgery at the University

kickback inducing a surgery that was actually alleged to have occurred. *See* AtriCure's Mem. Supp. Mot to Dismiss (hereinafter "Mot. to Dismiss") at 32, Doc. 91-1 at PageID 326. In short, the Complaint fails to plead the submission of a representative claim connected to such kickback schemes.

B. Relator Has Not Pled an AKS Violation

The Complaint also fails to plead with particularity an AKS violation. The Opposition's arguments to the contrary demonstrate that Relator's pled assumptions are untethered from the actual facts alleged.

For example, likely recognizing that AtriCure's reimbursement of physicians' expenses is the only possible kickback "scheme" that could possibly have induced one or more of the five surgeries, the Opposition argues at length that reimbursement of physician meal and travel expenses constitutes remuneration. But AtriCure never suggested otherwise.[8] Instead, AtriCure argued that Relator failed to allege that such payments were "illegal remuneration" because the Complaint lacks any facts showing that reimbursements were knowing and willing inducements for use of AtriCure's products (let alone government business).

The Opposition asks the Court to assume that all remuneration paid to doctors—which AtriCure discloses and is available to the public[9]—has an improper purpose. But medical device

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of Utah, who was calling on behalf of Dr. Kumpati"); ¶ 253 (asserting "on August 18, 2015 – as a further inducement, AtriCure paid for a third-party consultant to provide detailed billing assistance, gratis to Dr. Kumpati . . . [t]he third-party consultant's free services included assistance with reimbursement of Medicare claims"); ¶ 254 (alleging that a surgery was scheduled on September 29, 2015 at the George E. Whalen Department of Veterans Affairs Medical Center on a patient not alleged to be covered by Medicare).

[8] AtriCure did argue that the Complaint failed to plead remuneration sufficient to support other purported kickback schemes that were either not actually alleged to have occurred or had no independent value to the recipients. Mot. to Dismiss at 19-22, Doc. 91-1 at PageID 313-16. The Opposition does not confront the case law behind such arguments, and largely reiterates the extent to which certain goods and services were indeed fundamentally associated with AtriCure's devices. Regardless, as the Complaint does not allege these specific kickback schemes are connected to even hypothetical claims flowing from the five surgeries doctors performed or scheduled, they are not viable.

[9] Indeed, the Complaint admits the very food and lodging amounts purportedly linked to surgeries were "reported to CMS." Compl. ¶ 243 ("AtriCure reported to CMS that it paid at total of $450 for Dr. Tripathi's travel to St. Helena

company payments to physicians are not "*per se* illegal." *U.S. ex rel. Laucirica v. Stryker Corp.*, No. 1:09-cv-63, 2010 WL 1798321, at *5 (W.D. Mich. May 3, 2010). To sustain an FCA case premised on the AKS, a realtor must plead factual allegations making "the inference of illegal intent and conduct [] more plausible than the inference of legal intent and conduct." *Id*.

As the Complaint contains no such factual allegations, the Opposition is forced to parrot its pled labels and conclusory assertions: that payments were "kickbacks in violation of the AKS" and must have been "effective" because heart surgeons performed (or were scheduled to perform) heart surgeries using AtriCure products that were more expensive than the purported kickbacks.[10] Opp. at 11, Doc. 100 at PageID 408. But such labels and conclusory assertions cannot move a claim across the line of plausibility, let alone satisfy Rule 9(b)'s heightened pleading standard. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 1:11-cv-029, 2015 WL 1439054, at *8-9 (S.D. Ohio Mar. 27, 2015) (finding allegations that payments for speaking engagements and free meals were intended to induce referrals insufficient absent supporting facts like increased prescription volume); *see also* Mot. to Dismiss at 24, Doc. 91-1 at PageID 318.

The Opposition also makes much of a "vineyard program" Dr. Tripathi purportedly attended during "all-expenses paid trips to Napa Valley, in the heart of California's wine country,"

($239.91 on May 27 and $210.58 on May 28, 2015) and his lodging in Napa."); *id.* ¶ 248 ("Dr. Kumpati likewise received a number of kickbacks from AtriCure, beginning not later than 2014. AtriCure reported to CMS that in that year, AtriCure gave Dr. Kumpati $609 worth of travel and lodging on August 12, followed shortly thereafter by another $921 in travel and lodging on August 22. As further part of its kickback program, AtriCure provided $125 in food and beverage on January 25, 2014; $100 of food and beverage the following day (January 26); $33 in food and beverage on February 6; and $122 in food and beverage on February 8 of the same year.").

[10] Relator notes that inducement need only be "one purpose" of remuneration, but the Complaint fails to plead facts supporting the conclusion that any purpose of the remuneration was to obtain money via the referral of government healthcare business. *Cf. Millennium Radiology*, 2014 WL 4908275, at *7 (relator satisfied one purpose test by pleading that there was an "exclusive referral and marketing system" between defendant and a hospital whereby "in return for the continuous flow of patient referrals at various [] hospital facilities, [defendant] agreed to provide [hospital] free physician administrative services in excess of a million dollars").

and invites the Court to presume that it "clearly ha[d] no educational purpose or value relevant to cardiology." Opp. at 6, Doc. 100 at PageID 403. Yet the Complaint offers nothing but Relator's conjecture that AtriCure covered any bill or otherwise conferred value specific to Dr. Tripathi's attending such a "program" while visiting St. Helena (to the extent there was a bill at all). *See* Compl. ¶ 243 (indicating that AtriCure did not report paying costs associated with the vineyard program, but not even speculating what such costs would be). And the facts Relator does offer contradict his assumption that the program "clearly ha[d] no educational purpose." *See* Compl. ¶ 242 ("AtriCure paid for Dr. Tripathi to travel to St. Helena, California for a program at Defendant St. Helena Hospital and Napa's Silverado Vineyards"); Compl. ¶ 102 (describing "training events" for physicians at St. Helena Hospital); *see also* Opp. to Hospital Defendants' Mot. to Dismiss at 7, Doc. 99 at PageID 391 (showing flyer for an Afib educational event hosted by St. Helena at Wente Vineyard). Relator has not plead with particularity that the alleged vineyard program constitutes remuneration paid by AtriCure, let alone facts showing that any such remuneration was illegal.

Equally unavailing is Relator's *post hoc* attempt to cure his failure to plead the AKS "knowingly and willingly" requirement, which is distinct from the FCA's "knowingly" standard.[11] *Compare Millennium Radiology*, 2014 WL 4908275, at *3 ("Under the [FCA], the terms knowing and knowingly mean that a person with respect to information has actual knowledge of the

[11] The Opposition mixes these standards. *Compare* Opp. at 11-12, Doc. 100 at PageID 408-019 (addressing intent under the AKS while citing the FCA standard) *with id*. at 13-14 (coupling the AKS rule from *Millennium Radiology* with the FCA standard from *Lynch* and seemingly arguing that labels are sufficient to satisfy the AKS standard). Regardless, Relator's contention that he can satisfy "scienter" by simply labeling conduct "inducement" or "illegal kickbacks" is incorrect. *See* Opp. at 14, Doc. 100 at PageID 411. Labels and conclusions alone do not suffice—Relator must plead facts to support his conclusions. *See Suarez*, 2019 WL 4749967, at *13 ("[A]lthough the circumstances constituting fraud must be pleaded with particularity, a defendant's [m]alice, intent, knowledge, and other conditions of . . . mind may be alleged generally . . . [t]he law nonetheless requires a relator to allege facts supporting an inference that defendant intended to act in a way it knew was wrongful."); *see also*, *Ibanez*, 2015 WL 1439054, at *8 (a relator must plead "with particularity facts alleging that the illegal remuneration [] paid was intended to induce the utilization of federal-health-care services").

information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information, and requires no proof of specific intent to defraud") *with id.* at *8 (to plead a violation of the AKS, "there must be an allegation that the defendant acted with the purpose to commit a wrongful act"). As the Complaint included no clear allegation that AtriCure acted "with the purpose to commit a wrongful act," AtriCure assumed that the Complaint's references to off-label promotion were Relator's attempt to show AtriCure acted wrongfully. *See* Mot. to Dismiss at 25, Doc. 91-1 at PageID 319. The Opposition ignores that theory, asserting only that because AtriCure previously settled a *qui tam* that included a kickback allegation and was under a Corporate Integrity Agreement ("CIA") during the relevant period, "any violation of the AKS is, *per se*, intentional or at the very least, an 'aggravated form of gross negligence' or 'reckless disregard' of AtriCure's obligations to know and follow the law."[12] Opp. at 12, Doc. 100 at PageID 409. But that position confuses the FCA scienter standard with what the AKS requires: acting with the purpose to commit a wrongful act.[13] It also overlooks that (a) the promotional allegations recited in the settlement agreement do not overlap with those Relator attempts to connect with pled claims (physician payments for meals and travel), and (b) AtriCure specifically denied the allegations in the cited settlement agreement created liability.[14] Realtor's references to the CIA are even more unavailing. The CIA required AtriCure to have compliance policies and procedures in place, as well as hire an Independent Review Organization ("IRO") to

[12] For the avoidance of doubt, the settlement referenced in the Complaint and Opposition resolved a civil *qui tam*, not a "prosecution." *Cf.* Opp. at 3, Doc. 100 at PageID 400. Relator's assertion that the case involved the State Plaintiffs in this case is also incorrect. *Id.*

[13] To the extent it is intended to meet the AKS standard, Relator's assertion also relies on circular logic—AtriCure must have known what it was doing was wrong because it violated the AKS (which, itself, would have required action done for a wrongful purpose).

[14] The settlement and CIA are incorporated by reference in Relator's Complaint, *see* Compl. ¶ 84-87 & n.10 (citing https://oig.hhs.gov/fraud/cia/agreements/AtriCure inc 01272010.pdf), and the Opposition now asserts both are critical to pleading elements of Relator's claim, *see* Opp at 12, Doc. 100 at PageID 409. Accordingly, both may be considered at the motion to dismiss stage. *See Antoon*, 978 F. Supp. 2d at 887.

review its promotional practices and report violations to the government. If anything, the CIA contradicts the inference Relator posits—AtriCure must have thought the purported "nationwide" conduct Relator now labels "illegal" was permissible if it knew it was under such tight scrutiny. *Cf. Millennium Radiology*, 2014 WL 4908275, at *8 (facts alleging that legal counsel advised against the specific kickbacks satisfied "knowingly and willfully" requirement); *see also U.S. ex rel. Hart v. McKesson Corp.*, 2022 WL 1423476, at *14 (S.D.N.Y. May 5, 2022) ("Allegations that [defendant] knew remuneration to induce purchases was prohibited in general, however, cannot alone support a finding that [defendant] knew this particular course of conduct was unlawful.").

All in, the Opposition's arguments simply confirm that Relator's Complaint fails to allege an illegal AKS scheme, much less a scheme resulting in the submission of false claims. As such, Counts One, Two, and Three should be dismissed.

III. RELATOR'S CONCLUSORY CONSPIRACY AND STATE CLAIMS SHOULD BE DISMISSED

The Opposition barely addresses Relator's conspiracy and state claims, instead referring the Court to the brief in opposition to Hospital Defendants' Motion to Dismiss. Opp. at 19, Doc. 100 at PageID 416. But that brief does not to respond to the specific arguments made by AtriCure. As AtriCure pointed out in its motion, Relator failed to plead the existence of a plan or agreement between the Defendants to violate the FCA as required by section 3729(a)(1)(C)—in other words, "a plan to get false claims paid." Mot. to Dismiss at 34, Doc. 91-1 at PageID 328 (quoting *Ibanez*, 874 F.3d at 917). Relator argues only that Defendants benefited from the conduct alleged in the Complaint, not that they had a plan or agreement to violate the FCA. That is not sufficient to state a claim for conspiracy. *See Ibanez*, 874 F.3d at 917.

Relator's defense of his state claims is equally deficient. There he argues that the Complaint alleged a nationwide scheme, but he cannot identify a single false claim submitted to any state

payor. Opp. to Hospital Defendants' Mot. to Dismiss at 9-10, Doc. 99 at PageID 393-94. Relator also argues that the Texas Medicare Fraud Prevention Act sets out several "qualifying acts" that do not require presentment of a false claim. *Id*. at 10, PageID 394. Putting aside that Count Twenty-Nine (the Texas count) is explicitly premised upon the presentment of a false claim, *see* Compl. ¶¶ 463-65, Relator has not identified a single "qualifying act"—let alone any act in Texas. Like Relator's federal claim, the state law claims should be dismissed.

CONCLUSION

For the reasons stated above, and in AtriCure's Memorandum in Support, the Motion to Dismiss should be granted with prejudice.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 2, 2022, a copy of the foregoing was electronically filed with the Clerk of Court using the Court's electronic filing system. Notice of this filing will be sent to counsel of record by operation of the Court's electronic filing system, and the parties may access the filing through the Court's system.

/s/ Russell S. Sayre